OBJECTIVES: To assess clinical efficacy and cost-effectiveness of human recombinant interferon-α2b in neonates with intrauterine infections in neonatal intensive care unit (NICU). **METHODS:** We observed 151 neonates (gestational age (GA) 25-40 weeks) with severe intrauterine infections in NICU. Group 1 included 94 neonates with severe intrauterine infections treated with interferon-α2b, 150 000 IU per suppositorium twice a day per rectum during 7 days in addition to combined antibacterial and supportive therapy; group 2 consisted of 57 neonates under standard treatment without additional immunotherapy. Initially neonates of both groups were comparable. Effectiveness data were used to populate a decision model to estimate the cost-effectiveness of interferon-α2b and standard therapy. Direct and indirect costs were measured. Published cost data were applied to assess differences in treatment costs. **RESULTS:** Low mitogen-induced interferon-α production (<12 pg/ml) was detected in 25% [18%; 33%] of neonates with severe intrauterine infections, its association with significantly higher incidence of pneumonia ($p<0.001$), necrotizing enterocolitis ($p<0.001$) and urinary tract infections ($p=0.026$) was proved. Administration of human recombinant interferon-α2b to neonates, suffering from severe infections, provides improvement of mitogen-induced production of interferon-α, reduces hospital length of stay and mortality rates ($p=0.009$, OR = 0.21 [0.05; 0.67], RR = 0.26 [0.07; 0.69], NNT=8 [4; 29]). Interferon-α2b administration for severe early-onset neonatal infections decreases direct costs per patient by 20% (direct costs per patient € 6,802 and € 8,549 for interferon-α2b and control groups, respectively). Interferon-α2b administration for intrauterine infections leads to substantial cost savings (up to € 69,247 per patient). **CONCLUSIONS:** Immunotherapy with interferon-α2b is a cost-effective intervention improves the clinical course and outcome in case of severe intrauterine infections.

PIH23

A DISCRETE EVENT SIMULATION MODEL USED FOR PHARMACOECONOMIC EVALUATION OF OMEGAVEN® IN THE CHINESE SETTING

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OBJECTIVES: Several published studies have demonstrated that the supplementation of Omegaven® has better clinical outcomes in Systemic Inflammatory Response Syndrome (SIRS) or elective major surgery patients treated in Intensive Care Units (ICUs),with shorter average lengths of stay in hospital and reduced fatality rate , as compared to standard total parenteral nutrition (TPN) regimens. The objective of the simulation study was to evaluate the CE of the supplementation of Omegaven® vs standard TPN in the Chinese setting. **METHODS:** A discrete event simulation (DES) model was constructed to compare the nutritional strategies in elective surgery and SIRS patients, by combining outcomes recorded in 79 elective major surgical patients and 56 SIRS patients receiving TPN in the surgical ICU of a tertiary hospital in Shanghai. Omegaven® efficacy estimates from a random effects Bayesian meta-analysis on Chinese and international clinical trials, and Chinese cost data collected in the same hospital, comprising ICU and general ward costs, and the cost for TPN. **RESULTS:** Omegaven® showed being effective in reducing fatality rate and total hospital length of stay (- 2.8 and -2.5 days) in both surgical and SIRS patients. In the SIRS group, the treatment could avoid 5.7 deaths every 100 patients. Reduced hospitalizations costs completely offset treatment cost, with a saving associated with Omegaven® of about 8,000 and 6,800 RMB in surgical and SIRS patients, respectively. **CONCLUSIONS:** The supplementation of Omegaven® can be considered dominant versus standard TPN, as the results of DES show that a mean increase of the effectiveness is associated with a mean decrease of the costs.

PIH24

ECONOMIC EVALUATION OF ULIPRISTAL ACETATE TABLETS FOR THE TREATMENT OF PATIENTS WITH MODERATE AND SEVERE SYMPTOMS OF UTERINE FIBROIDS

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OBJECTIVES: Ulipristal acetate - a selective progesterone receptor modulator - was proved to be effective for 3 month pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The aim of this analysis was to assess the cost-effectiveness of ulipristal acetate 5 mg as an add-on therapy to standard pre-surgical treatment in Hungary. **METHODS:** A Markov state-transition economic model was developed over 10 year time horizon. Ulipristal acetate was compared to 1) pre-surgical observation, and 2) immediate hysterectomy. The model comprises mutually exclusive health states: no/mild bleeding disorder, heavy bleeding disorder, persistent heavy bleeding disorder, myomectomy, post-myomectomy with no/mild bleeding disorder, post-myomectomy with heavy bleeding disorder, hysterectomy, post-hysterectomy, post-menopausa and death. Transition probabilities and utility values were drawn from the Pearl I clinical trial and scientific literature. Resource utilisation and unit costs were derived from the consensus panel of clinical experts and National Health Insurance Fund tariffs and publications. Costs and QALYs were discounted at a yearly rate of 3.5%. **RESULTS:** Addition of 3 month ulipristal acetate to the standard pre-operative therapy was predicted to achieve an additional 0.019 QALYs compared to observation at an estimated incremental cost of €376, resulting an incremental cost of 20,180 €/QALY. Results were most sensitive to the utility value of post-hysterectomy, but robust to changes in further model parameters. When 3 month of therapy was compared to immediate hysterectomy without any observation period, the ICER was reduced to 6,095 €/QALY. **CONCLUSIONS:** The analysis suggests that adding ulipristal acetate treatment to standard pre-surgical therapy represents good value for money according to currently accepted cost-effectiveness criterion in Hungary. Inclusion of societal benefits may considerably reduce the cost-effectiveness ratio, however further evidence from observational studies is needed to capture potential benefits of ulipristal acetate therapy on fertility.

PIH25

TESTOSTERONE REPLACEMENT THERAPY IN MALES WITH HYPOGONADISM IN SWEDEN: A COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: Testosterone replacement therapy (TRT) is recommended for the treatment of primary and secondary hypogonadism. However, long-term implications of this therapy have not been investigated extensively. Therefore, the aim of this analysis was to evaluate health outcomes and costs associated with life-long TRT in patients suffering from Klinefelter syndrome and late-onset hypogonadism (LOH). **METHODS:** A Markov model was developed to assess cost-effectiveness of testosterone undecanoate (TU) depot injection treatment compared with no treatment. Health outcomes and associated costs were modeled in monthly cycles per each patient individually along life-time horizon. Modeled health scenarios included development of type 2 diabetes, depression, cardiovascular and cerebrovascular complications and fractures. Results were expressed in terms of incremental quality of life years (QALY) gained, incremental costs and incremental cost-effectiveness ratio (ICER). Analysis was performed for the Swedish health care settings from health care payer's and societal perspective. One way sensitivity analyses served to evaluate robustness of the results. **RESULTS:** TU depot injection in Klinefelter population yielded a gain of 1.67 QALYs compared to the no-treatment at an incremental cost of 257,757 SEK (28,176 EUR), showing an ICER of 154,459 SEK (16,884 EUR) per QALY gained. Outcomes in LOH population estimated benefits of TRT at 180,400 SEK (19,719 EUR) per QALY gained. Results showed to be considerably robust when tested in sensitivity analysis. Variation of relative risk to develop type 2 diabetes had the highest impact on long-term outcomes in both patient groups. **CONCLUSIONS:** TRT treatment proved its efficacy across many clinical trials. This analysis suggests that life-long TU depot injection therapy is cost-effective in Sweden for patients with hypogonadism. Hence, it can support clinicians in decision making when considering appropriate treatment strategies for patients with testosterone deficiency.

PIH26

SOCIAL IMPACT OF ADALIMUMAB IN THE ITALIAN PERSPECTIVE

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OBJECTIVES: The assessment of indirect costs represents an extremely important issue when managing chronic diseases. Patients' lost productivity is often overlooked by decison makers, although it is fundamental for the complete estimation of the true economic impact of disease. The objective of this study is to estimate the social savings obtained with Adalimumab compared to standard therapies for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and psoriasis, in the Italian population. **METHODS:** Five different economic models have been developed to estimate the cost utility of Adalimumab vs standard care for each of the diseases (the economic models were developed by external consultants). Both Italian National Health System (direct costs) and social (direct costs + loss of productivity) perspectives were adopted. For each pathology models have calculated the loss of productivity per pt/year with standard therapy and with Adalimumab. A sensitivity analysis, based on the variability of model parameters, was performed in order to assess the robustness of the results. **RESULTS:** In the base case scenario, the average annual social cost (weighted for prevalence of eligible patients for biologic treatment of each pathology) per patient amounted to €1274,25 if treated with standard care, compared with €569,48 if treated with Adalimumab. Adalimumab treatment would allow –9,4% (€42 millions) reduction of the total social cost assuming 17% of market penetration for patients eligible for biologic use. Sensitivity analysis shows that annual saving in social costs can vary from 8,1 to 11,9% assuming an average market share of 17% of Adalimumab. **CONCLUSIONS:** Adalimumab has a significant impact in reducing social costs for all the diseases considered in this study. These aspects, often neglected in decision makers' assessments, should instead be included in the overall evaluation of benefits, of innovative technologies as biologic drugs.

PIH27

COST ANALYSIS OF NEONATAL AND PEDIATRIC PARENTERAL NUTRITION IN BELGIUM

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OBJECTIVES: Parenteral nutrition (PN) is critical in neonatal and pediatric care for patients unable to tolerate enteral feeding. Considering the limited cost data on pediatric PN in Belgium, the aim of this study was to evaluate total Belgian PN costs when admixtures are produced in-hospital, either in a pharmacy or in the ward. **METHODS:** A cost-model was used to assess the following: nutrient costs; labor costs (personnel costs to prescribe and prepare); disposable costs (supplies used);